

REMARKS/ARGUMENTS

Claims 22-24, 26-28, 31, 52, 54-55 and 61-63 are active. Claims 25, 30, 36-51 and 56-60 have been withdrawn from consideration. Claims 29, 32-36 and 53 have been cancelled. Claims 23-26, 52, and 54 have been revised for clarity or have been edited as suggested by the Examiner. Support for the range 10 to 300 bp in claim 52 is found at the top of page 14 of the specification. No new matter is believed to have been introduced. Favorable consideration of this amendment and allowance of the case are respectfully requested.

Restriction/Election

The Applicants previously elected without traverse **Group I**, claims 22-24, 26-36 and 52-55, directed to adenovirus products and methods involving the deletion of residues 311-319 of SEQ ID NO: 2, and the species **(i) type 2 canine adenovirus and (ii) cat**. The Applicants understand that additional species will be rejoined and examined upon an indication of allowability for a generic claim reading on the elected species. The Applicants respectfully request that the claims of the nonelected group(s) or other withdrawn subject matter which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

Rejection—35 U.S.C. §112, second paragraph

Claims 23, 24 and 52-55 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Objection—Claims

Claims 52 and 54 were objected to as being unclear. This objection is moot in view of the adoption of the Examiner's proposed wording.

Rejection—35 U.S.C. §102

Claims 22, 26-29, 31 and 52-55 were rejected under 35 U.S.C. 102(b) as being anticipated by Soudais, et al., JASGT 3:631 (2001). The Applicants respectfully traverse this rejection for the reasons explained below.

Independent claim 22 relates to a recombinant CAV2 adenovirus which replicates and **produces infectious viral particles** but the recombinant virus disclosed by Soudais do not.

Soudais disclose the generation of several mutants with different combinations of deletions of the encapsidation signals. These mutants are listed and represented in Figure 2b and were generated (cf. *Construction of packaging mutants*. page 632, 2<sup>nd</sup> column) by recombination between the CAV genome and transfer plasmids which were themselves derived from the plasmid pCAVGFP. Plasmid pCAVGFP contains the CAV-2 ITR and packaging domain from bp 1 to 411, followed by a 1.9-kb EGFP expression cassette, and by the CAV-2 E2B region.

**This means that it does not comprise the E1 region.** As a consequence, the recombinant viruses obtained from this plasmid do not comprise the E1 region and that the disclosed recombinant viruses are **unable to produce infectious viral particles**.

This is further indicated by Soudais which specify that "All the vectors in this study are **replication-defective** as the E1 region is functionally deleted" (page 632, 2<sup>nd</sup> column, lines 43-44). This also is clearly apparent from Figure 2b which shows that in all the vectors

the E1 coding region of CAV-2 (represented at the top of Figure 2b) beginning at position 500, is absent and replaced by the GFP cassette.

In contrast, vectors of instant claim 22 have a deletion which, at most, ends before the beginning of the sequence encoding E1A: they always comprise the full length E1 coding region. Accordingly, Soudais et al. do not anticipate the recombinant adenoviruses of independent claim 22 and of the claims which depend on claim 22 and this rejection cannot be sustained.

Rejection—35 U.S.C. §103

Claims 61-63 were rejected under 35 U.S.C. 103(a) as being unpatentable over Soudais, et al., JASGT 3:631 (2001), in view of Haddada, et al., U.S. Patent No. 6,294,377. This rejection is moot in view of the amendments above and would not apply to the new claims.

As apparent from the discussion above, Soudais does not teach the recombinant adenovirus of claim 22.

Haddada indicates that adenoviral vectors expressing antigenic peptides can be used to induce an immune response in humans against the expressed adenoviral antigenic peptides. However, like Soudais, Haddada does not disclose or suggest the recombinant canine type 2 adenovirus of independent claim 22. Rather, the adenoviral vectors described in Soudais are fundamentally different from those of the invention and cannot render the methods of claims 61-63 obvious. These fundamental differences in the Haddada expression vectors are acknowledged in the OA on page 5, lines 15-16.

In addition to these structural and functional differences, the person of ordinary skill would not have replaced the defective vectors described in Soudais by *replicative* vectors given that the U.S. patent 6,294,377 very clearly teach that the vectors should preferably be defective (see column 2, last paragraph). Therefore, the cited prior art does not teach all the elements of the

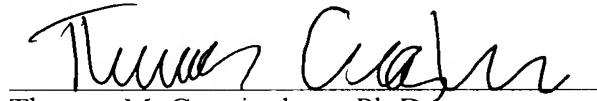
invention and does not suggest or provide a reasonable expectation of success for the method of claims 61-63. Thus, this rejection cannot be sustained.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



Thomas M. Cunningham, Ph.D.  
Registration No. 45,394

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)